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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
OSTRUP, CLINTON T	
ART UNIT	PAPER NUMBER
3771	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,759	FEINER ET AL.	
	Examiner	Art Unit	
	CLINTON OSTRUP	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 December 2004* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date ____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is in response to the amendment filed April 20, 2009. As directed by the amendment, claims 1, 10, and 16 have been amended and claim 20 ahs been added. Thus, claims 1-20 are pending in this application.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sommer et al. (WO 01/85241A1), based on the machine translation provided by the European Patent Office, and further in view of Danby et al., (5,680,111).

Regarding claims 1 & 20, Sommer discloses a nebulizer device (figure 1) for detecting the parameters of an aerosol (flow) comprising a transmitting means (7) which is disposed on a body (5) that at least partially surrounds an aerosol resting area (inside mouthpiece), and which emits radiation (infrared light) into said aerosol resting area through a transparent material; a first receiving means (8), which is disposed on the body (5) that at least partially surrounds said aerosol resting area (inside mouthpiece), which is disposed in relation to said transmitting means (7) so as to primarily receive transmission radiation (infrared light) , and which emits a first analysis signal (output signal of 8) that corresponds to the intensity of the received transmission radiation; and a control means (9), to which the output signals (via 8) are supplied and which analyses

the output signals in order to determine the parameters (flow) of an aerosol in said aerosol resting area. See: figures 1-3 & 12.

However, Sommer lacks the specific teaching that the droplets from the aerosol adhere to the body in an area through which the radiation is transmitted from the transmitting means into the aerosol resting area and a second receiving means disposed on the body that at least partially surrounds the aerosol resting area; which is disposed in relation to said transmitting means so as to primarily receive scattered radiation and which emits a second analysis signal that corresponds to the intensity of the received scattered radiation. Sommer also lacks the specific teaching that the droplets from the aerosol adhere to the body in an area through which the radiation is transmitted from the transmitting means into the aerosol resting area

Danby et al. teaches a device for detecting air in a tubular system that uses a transmitter with two receivers and describes how the system works well with transparent or translucent tubes. Danby teaches how the one receiver is at a ninety degree angle in relation to the transmitter and the other receiver is at a one hundred and eighty degree angle in relation to the transmitter. Danby teaches that both receivers are connected to a processor which processes the light receivers' outputs to detect air in the tubing. See: abstract, col. 3, lines 28-54; col. 4, line 58 - col. 5, line 6 and figures 3 & 8.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the nebulizer flow detection device disclosed by Sommer by utilizing a pair of sensors disposed perpendicular to each other, as taught by Danby, in order to provide a nebulizer flow detector with increased precision.

Regarding the use of a transmitting means which emits radiation into an aerosol resting area through a translucent material, Danby contemplates using both transparent and translucent materials. Regarding the droplets from the aerosol adhering to the body in an area through which the radiation is transmitted from the transmitting means into the aerosol resting area, it is the examiners position that the device disclosed by Sommer, which utilizes a body (5) in an area (near mouthpiece) through which the radiation (from 7) is transmitted from the transmitting means (7) into the aerosol resting area (inside 5) and the droplets from the aerosol would be expected to contact the inner walls of the mouthpiece and adhere thereto.

Regarding claim 2, Sommer discloses a transmitting means (7) emits radiation (infrared light) and Danby teaches the first translucent wall section (14 or 15) of the body (5 of Sommer) surrounding the aerosol resting area (inside mouthpiece of Sommer).

Regarding claim 3, the combined references teach a first receiving means (20b of Danby) receives the transmission radiation through a second wall section (adjacent 20b) of the body (5 of Sommer) surrounding the aerosol resting area (inside mouthpiece of Sommer.

Regarding claim 4, the combined references teach a second receiving means (20a of Danby) that receives the scattered radiation (infrared light) through a third wall section (adjacent 20a) of the body (5 of Sommer) surrounding the aerosol resting area (inside mouthpiece of Sommer).

Regarding claim 5, the combined references teach a body (5 of Sommer) surrounding the aerosol resting area (inside mouthpiece of Sommer) and Danby teaches a transparent or translucent material can be used. See: See: col. 1, line 65 - col. 2, line 13 & abstract of Danby.

Regarding claim 6, the combined references teach a body (5 of Sommer) surrounding the aerosol resting area (inside mouthpiece of Sommer) is made of a transparent material and Danby teaches a transmitting means (21 of Danby), that functions well whether it is made of a transparent or a translucent material, through which radiation is emitted. See: col. 1, line 65 - col. 2, line 13 & abstract of Danby.

Regarding claim 7, the Danby teaches a first receiving means (20b of Danby) and teaches that the device works reliably well using transparent of translucent materials, thus it would be obvious to provide a surface made of a translucent material, through which the radiation is received because the system provides reliable detection of air bubbles through both transparent and translucent materials.

Regarding claim 8, Danby teaches a second receiving means (20a of Danby) and teaches that the device works reliably well using transparent of translucent materials, thus it would be obvious to provide a surface made of a translucent material, through which the radiation is received because the system provides reliable detection of air bubbles through both transparent and translucent materials.

Regarding claim 9, Sommer discloses a control means (9) that activates the transmitting means to emit the radiation into the aerosol resting area (inside mouthpiece of Sommer).

Regarding claim 10, Sommer discloses a control means (9) that activates the transmitting means (7) such that first time periods in which the transmitting means emits radiation (infrared light) into the aerosol resting area (inside mouthpiece of Sommer), alternate with second time periods (when not in use) in which the transmitting means (7 does not emit radiation into the aerosol resting area (inside mouthpiece).

Regarding claim 11, when the transmitter (7 of Sommer) is not transmitting light, it is reasonably expected that during this (not in use) second time period the control means (9 of Sommer) determines the proportion of ambient light in the output signals (as ambient light is the only light being received by the receiver when the transmitter is not transmitting) of the first (20b of Darby) and/or second (20a or Darby) receiving means.

Regarding claim 12, since ambient light is present when the receivers are receiving the infrared light, it is reasonably expected that the control means (9 of Sommer) which receives signals from the receivers, would make use of the proportion of ambient light (the amount of ambient light sensed in combination with the amount of light received by the transmitter) when analyzing the output signals of the first and second receiving means (20b & 20a of Darby).

Regarding claim 13, Sommer discloses a control means (9) that is capable of determining the difference of the output signal of the first receiving means (20b) and the first ambient light proportion (portion of ambient light surrounding 20b prior to the transmitter transmitting infrared light) and/or the difference of the output signal of the

second receiving means (20a) and the second ambient light proportion (ambient light surrounding 20a prior to the transmitter transmitting infrared light).

Regarding claim 14, Sommer discloses a control means (9) that is capable of forming a quotient from the difference of the output signal of the second receiving means (20a) and the second ambient light proportion (ambient light surrounding 20a prior to the transmitter transmitting infrared light) and the difference of the output signal of the first receiving means (20b) and the first ambient light proportion (ambient light surrounding 20b prior to the transmitter transmitting infrared light).

Regarding claim 15, Sommer discloses a control means (9) that is capable of forming a quotient from the output signal of the second receiving means (20a) and the output signal of the first receiving means (20b) and it would be obvious to one having ordinary skill in the art to form a quotient in order to determine the signal strength coming from each receiver to the controller.

Regarding claim 16, Sommer discloses infrared light as the radiation emitted by the transmitting means (7).

Regarding claim 17, Sommer discloses a body (5) surrounding the aerosol resting area (inside mouthpiece) that is a mouthpiece (5) for an inhalation therapy device.

Regarding claim 18, Sommer discloses nebulizer devices with a nebulizer nozzle (40 of figure 1) and a membrane nebulizer (52 of figure 12).

Regarding claim 19, Sommer discloses the control means (9) is connected with a compressor (2) for the nebulizer nozzle (40 of figure 1) or with an excitation device (56 of figure 12) for the membrane (52) nebulizer.

Response to Arguments

Applicant's arguments filed April 20, 2009 have been fully considered but they are not persuasive.

Applicants argue that Sommer lacks a first receiving means which is disposed in relation to the transmitting means so as to primarily receive transmission. The examiner respectfully disagrees as the a first receiving means (8), which is disposed on the body (5) that at least partially surrounds said aerosol resting area (inside mouthpiece), which is disposed in relation to said transmitting means (7) so as to primarily (as its primary function) receive transmission (infrared light radiation transmitted by transmitting means 7) radiation (infrared light). Although the light is reflected radiation, the receiving means is located so as to primarily (as its primary function) receive transmission (infrared light radiation transmitted by transmitting means 7) radiation (infrared light).

Regarding applicant's argument that Sommer does not disclose or suggest a transmitting means which emits radiation into the aerosol resting area through a translucent material, the examiner respectfully agrees.

However, Danby was used to teach a device in a tubular system that uses a transmitter with two receivers and describes how the system works well with transparent or translucent tubes. Danby teaches how the one receiver is at a ninety degree angle in relation to the transmitter and the other receiver is at a one hundred and eighty degree

angle in relation to the transmitter. Danby teaches that both receivers are connected to a processor which processes the light receivers' outputs to detect air in the tubing. See: abstract, col. 3, lines 28-54; col. 4, line 58 - col. 5, line 6 and figures 3 & 8.

Applicant's argument that Danby relates to detection of air bubbles in a fluid carried by tubing, and is therefore unrelated to the problem of detecting an aerosol, has not been taken well because the transmitting and receiving radiation in an aerosol was disclosed by Sommer and Danby was merely used to show that the transmitting and receiving means wherein the device has one receiver that is at a ninety degree angle in relation to the transmitter and another receiver at a one hundred and eighty degree angle in relation to the transmitter would provide flow detection with increased precision.

Regarding applicants argument that Danby appears to suggest transparent tubing and translucent tubing are interchangeable, the examiner agrees and suggests one having ordinary skill in the art would easily and readily recognize that the transparent tube of Sommer could be substituted for a translucent tube as taught by Danby.

Therefore, as stated above, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the nebulizer flow detection device disclosed by Sommer by utilizing a transmitter with a pair of sensors disposed perpendicular to each other, as taught by Danby, in order to provide a nebulizer flow detector with increased precision.

Conclusion

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON OSTRUP whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771